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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/865,879	05/25/2001	Igor B. Roninson	99,216-H	5092

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EXAMINER

YU, MISOOK

ART UNIT PAPER NUMBER

1642

DATE MAILED: 02/27/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/865,879

Applicant(s)

RONINSON ET AL.

Examiner

MISOOK YU, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8,9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 8-18 are pending and examined on merits.

Specification

Objection of the specification is withdrawn because applicant corrected all of the objected defects with the amendment filed on 11-15-2002.

Claim Rejections - 35 USC § 112

Rejection of claims under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** because applicant clarified what the metes and bounds are for the claimed invention.

Rejection of claims 8-16 and 18 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for MCF-7 cells, does not reasonably provide enablement for any mammalian cells **is withdrawn** because WO 96/23080 (IDS filed on 7-10-2002), Simon et al (IDS, 1996, Cancer Research, vol. 56, pages 5369-74), and Hembree et al (IDS filed on 7-10-2002, and Cancer Research vol. 56, pages 1793-9) teach screening a compound that induces expression of a retinoid-inducible gene is a routine matter in the art.

Rejection of claim 17 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention **is withdrawn** because WO 96/23080 (IDS filed on 7-10-2002), Simon et al (IDS, 1996, Cancer Research, vol. 56, pages 5369-74), and Hembree et al (IDS filed on 7-10-2002, and Cancer Research vol. 56, pages 1793-9) teach that devising an assay of capable of screening a compound that induces expression of a retinoid-inducible gene is a routine matter in the art .

Rejection of claim 17 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one

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skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention **is withdrawn** because WO 96/23080 (IDS filed on 7-10-2002), Simon et al (IDS, 1996, Cancer Research, vol. 56, pages 5369-74), and Hembree et al (IDS filed on 7-10-2002, and Cancer Research vol. 56, pages 1793-9) teach that devising an assay of capable of screening a compound that induces expression of a retinoid-inducible gene is a routine matter in the art .

Claim Rejections - 35 USC § 103

Claims 8-16 and 18 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Adamo et al (1992, Endocrinology 131:1858-1866), Miller (1998, Cancer 83: 1471-82), Han et al (1997, J. Biol. Chem. 272: 13711-13716), and US Pat. 5,795,726 (18 Aug.1998).

Applicant argues that the references cited in the Office action alone or in combination do not teach the claimed invention. This argument is not convincing because Adamo et al, Han et al (1997, J. Biol. Chem. 272: 13711-13716), and US Pat. 5,795,726 teach the active steps of instant invention (note pages 7 and 8 of the previous Office action) and Miller further teaches why one in ordinary skill in the art would be motivated to do the task stated in the preamble of the instant claims.

Applicant further argues with the limitation not specified in the instant claims, i.e., the instant invention is to identify **non-retinoid compounds** and further argues that Miller does not teach identification of non-retinoid compounds. Applicant is requested to read carefully the active steps of instant claim 8 (a) and instant claim 12 (a), which say any compound (not just non-retinoid compounds) is dumped in the culture cells of the screening assay. Also note the preamble of the instant claims.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Simon et al (IDS, 1996, Cancer Research, vol. 56, pages 5369-74) as evidenced by Montemurro et al (1999, British Journal of Haematology, vol. 107, pages 294-299, abstract only).

The claims are drawn to method of screening useful compounds using mammalian cells transfected with recombinant expression construct encoding a report gene operatively linked to a promoter from a gene whose expression is induced by a retinoid, wherein the promoter does not contain a RARE site.

Simon et al teach method of screening useful compounds using mammalian cells transfected with recombinant expression construct encoding a report gene operatively linked to a promoter from a gene whose expression is induced by a retinoid. Note Fig. 4. Simon et al do not teach the promoter disclosed at Fig. 4 is induced by a retinoid but it is inherent property of the promoter because Montemurro et al teach that the identical promoter is induced by retinoids. Further it appears that the promoter used in Fig. 4 of Simon et al does not contain a RARE site defined at page 13 lines 17-21 of the instant specification. The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the composition of the prior art does not possess the same material, structural and functional characteristics of the instantly claimed materials used in the screening method. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed composition is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claims 8-12, 14, 16, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/23080 (IDS filed on 7-10-2002).

The claims are drawn to method of screening useful compounds using mammalian cells (claims 12, 14, 16, and 18) or mammalian transfected with

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recombinant expression construct encoding a report gene operatively linked to a promoter from a gene whose expression is induced by a retinoid, wherein the promoter does not contain a RARE site (claims 8-11). WO 96/23080 teaches method of screening useful compounds using mammalian cells having TIG1 promoter or cells transfected with recombinant expression construct encoding a report gene operatively linked to a promoter from a gene whose expression is induced by a retinoid. WO 96/23080 teaches at page 1 lines 9-13 that psoriasis is hyperproliferative disorder and the compound used in Example 9 at pages 19-24 were able to treat psoriasis, which indicates that it inhibited growth of the cell thereby (limitation of instant claim 14). Note pages 9-36 for various screening strategies and mammalian cells used. Further it appears that the TIG1 does not contain a RARE site defined at page 13 lines 17-21 of the instant specification. The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the composition of the prior art does not possess the same material, structural and functional characteristics of the instantly claimed materials used in the screening method. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed composition is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claims 12-18 are rejected under 35 U.S.C. 102(b) as being anticipated by either Hembree et al (IDS filed on 7-10-2002, and Cancer Research vol. 56, pages 1793-9) or Shang et al (IDS filed on 7-10-2002).

The claims are drawn to method of screening useful compounds that induces expression of retinoid-induced gene in a mammalian cell, wherein the promoter does not contain a RARE site.

Hembree et al teach method of screening useful compounds that induces expression of retinoid-induced gene in a mammalian cell, wherein the promoter does not contain a RARE site. Note Fig.1-8.

Shang et al teach method of screening useful compounds that induces expression of retinoid-induced gene in a mammalian cell, wherein the promoter does not contain a RARE site. See the entire article, especially Fig. 1, 4, 6, and 7.

Thus, either Hembree et al or Shang et al anticipates the instant claims.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 7-10-2002 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu

February 14, 2003


SHEELA HUFF
PRIMARY EXAMINER